

carries thereon a plurality of immunoassay test strips so mounted that a first portion of the test strips receives the fluid sample and a second portion of the test strips visually indicates presence or absence of a selected drug of abuse. In these test strips, the fluid sample moves by capillary action through the material of each test strip from the first portion of the strip to the second or test portion of the strip. (See page 13, lines 10-11 of the Specification.) Such test strips are generally referred to as "lateral flow" strips.

Boger discloses a holder for positioning and retaining multiple, individual reagent test pads or devices. The holder is provided with a number of openings to expose each reagent test pad for the application of a fluid sample. The ends of the test devices 20 project outwardly of the holder as shown in Fig. 2 of the Boger drawings and function as handle portions. Preferably, the sample to be tested is applied to each of the individual test pads but Boger also suggests that the entire holder can be dipped into the sample to be tested. While Boger suggests that these test devices might be of an immunochemical structure, this statement only means that these devices could be made for an antigen-antibody reaction and does not suggest in any way that such test pads are lateral flow. The nature of these test pads is clearly described in Column 1, lines 44-64 of Boger. There is no suggestion or indication in the entire Boger patent that his test devices are of a lateral flow structure.

Sun, does disclose a lateral flow immunoassay test strip which is completely enclosed between two pieces of plastic that are welded together to fabricate a plastic housing of a test device. No portions of a test strip in Sun are exposed to the

atmosphere through suitably arranged openings in a front surface of the test device. As clearly shown in Fig. 1a, there is an opening in the plastic housing which is a reception cavity for the fluid sample to be tested and the fluid sample must then flow through a passage 108 before coming into contact with the test strip 102. Thus, Sun is concerned only with providing a housing for an immunoassay test strip wherein the fluid sample will flow by capillary action, or lateral flow from one portion of the test strip to another.

Thus, the test devices in the holder of Boger are reagent pads which are entirely and completely dissimilar and different from the lateral flow immunoassay test strips in Sun. There is no suggestion in the prior art to one versed in the art of mounting a lateral flow immunoassay test strip in a holder for reagent test pads. These are two entirely different test devices.

It is noted that in Sun no portion of an immunoassay test strip is exposed to the atmosphere. There is no indication to one versed in the art of putting openings, such as disclosed in Boger, in the Sun plastic holder when the function of the test strips in Sun are wholly different from the test pads in Boger. In Sun, the fluid sample is applied through an opening and then flows through a passage to the test strip itself. Since the test strip in Sun functions by lateral flow and the test pads in Boger merely require the application of test fluid to each independent test pad, it would appear that these significant differences between these two test devices would not provide any teaching for substituting one for the other in a manner as disclosed and claimed by applicant.

Boger merely shows openings to expose the test pad and to enable a fluid sample to be applied to the test pad. Boger further states that in his Fig. 3 "a holder for single pad reagent devices is shown in which the top member of the holder contains a single opening 22-22 for each reagent test device." There are what appear to be on the top member of the Boger device rectangular recesses or other rectangular structures but there is not the slightest indication in the specification as to what these rectangular structures are, and hence, there clearly is no teaching of second openings of the top surface of Boger.

During the interview it was pointed out that there was a continuous flow of the fluid sample through the test strip of applicant whereas in Boger, the fluid sample as merely applied to the test pad absorbed therein and bring about a chemical reaction to manifest a detectable response, such as a color change.

It is thus submitted, that because the test pad in Boger is completely different from the lateral flow test strip of Sun that it is most unlikely one versed in the art would look to a holder of test pads in which to mount lateral test strips.

Applicant has thus invented a greatly simplified test card which is particularly adapted for insertion through an opening in the top of a container to contact a fluid sample within the container or to place the test card in direct contact with a reservoir of fluid samples. The immunoassay test strips are enclosed within the test card so as to be completely protected and the only portions of the test strips visible to the atmosphere are the sample receiving and test portions which are visible through spaced openings in the front space of the test card.

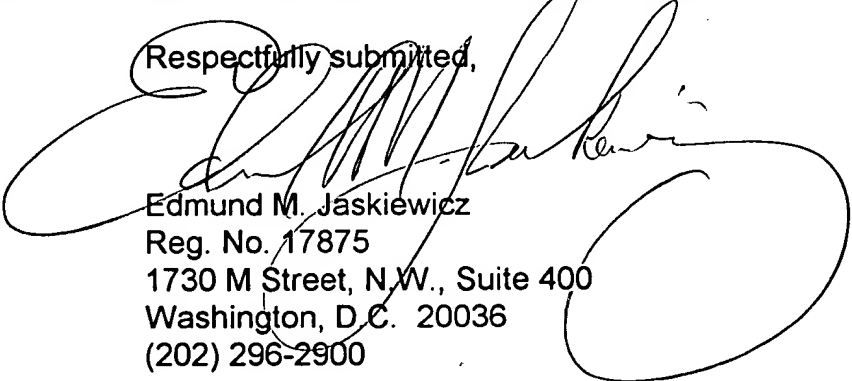
Claim 16 has been amended to clearly recite that applicant's immunoassay test

strips are of the lateral flow type wherein the fluid sample flows or moves by capillary action between the two portions of the test strip.

In view of this amendment and the foregoing Remarks, it is believed that applicant's claims define patentably over the cited references, taken singly or in combination and an early and favorable response from the Examiner is respectfully requested.

A Notice of Appeal was filed in this case on December 10, 1999 and the Appeal Brief was due in two months or on February 10, 2000. Accordingly, a Petition for Extension of Time together with the requisite fee is attached to this paper to extend the time for filing of the Appeal Brief and to maintain the pendency of this application.

Respectfully submitted,



Edmund M. Jaskiewicz  
Reg. No. 17875  
1730 M Street, N.W., Suite 400  
Washington, D.C. 20036  
(202) 296-2900

RECEIVED  
MAR 24 2000  
TC 1600 MAIL ROOM